

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

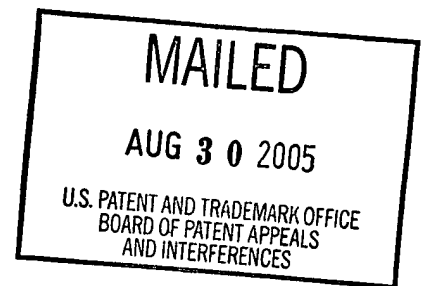
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte LARS WIKLUND, TORBJORN KARLSSON,
and ANDERS NORDGREN

Appeal No. 2005-1097
Application No. 09/773,394

ON BRIEF



Before ELLIS, SCHEINER, and MILLS Administrative Patent Judges.

MILLS, Administrative Patent Judge.

ON REMAND TO THE EXAMINER

Our consideration of the record leads us to conclude that this case is not in condition for a decision on appeal. Accordingly, we remand the application to the examiner to consider the following issues and take appropriate action.

Claims 1-2 and 4-21, which are all of the claims pending in this application, are on appeal.

Claim 1 is illustrative of the claims on appeal and reads as follows:

1. A method of preserving bodily protein stores in a catabolic patient, comprising the concomitant administration of a pair of pharmaceutical agents consisting essentially of (a) a first composition containing at least one of α -ketoglutarate and α -ketoglutaric acid and being devoid of ammonium, and (b) a second

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composition containing ammonium and being devoid of α -ketoglutarate and α -ketoglutaric acid, the amounts of the pair being effective to preserve skeletal muscle.

The prior art references cited by the examiner are:

Veech	5,719,119	Feb. 17, 1998
Vinnars	5,310,768	May 10, 1994

DISCUSSION

Claims 1-2 and 4-21 stand rejected under 35 U.S.C. §103(a), as obvious over Veech and Vinnars.

However, prior to consideration of, and application of the prior art in the present case, the examiner should take a step back and reinterpret the pending claims. It would appear that at the present time, on the record before us, a proper claim interpretation has not been performed.

It is recommended that the examiner review the specification carefully prior to interpreting the pending claims. For example, claim 1 requires "concomitant administration of a pair of pharmaceutical agents." Appellants appear to argue that "the combination of references advanced in this rejection does not teach or suggest the use of two separate compositions." Brief, page 9. However, it does not appear that claim 1, when interpreted in view of the specification, requires the administration of two separate compositions. The claim would appear to require administration of a pair of pharmaceutical agents or these agents in a composition, and not separate

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administration of two compositions.¹ It would also appear that neither the specification, nor the claim language itself indicates that the concomitantly administered pharmaceutical agents must be administered separately and that they cannot be administered in a single formulation including the two compositions. We note the specification, page 4, states that the term “‘in combination’ refers to the administration of α -ketoglutaric acid and ammonium in temporal dependence of each other, the one or other or both being administered continuously or intermittently.” This definition does not require “separate” administration. Nor are the claims limited to intravenous administration of these compositions.

In addition, the method of claim 1 is a method of preserving bodily protein stores in a catabolic patient, **comprising** the concomitant administration of a pair of pharmaceutical agents consisting essentially of (a) a first composition containing at least one of α -ketoglutarate and α -ketoglutaric acid and being devoid of ammonium, and (b) a second composition containing ammonium and being devoid of α -ketoglutarate and α -ketoglutaric acid, the amounts of the pair being effective to preserve skeletal muscle.

¹ We note the claims as originally filed recited concomitant administration of two compounds. Appellants amended claim 1 in an amendment filed October 31, 2003, to recite a method of administering two compositions without indicating support in the specification for this amendment. The examiner may want to consider questioning support in the specification for this amendment.

While the pair of pharmaceutical agents “consists essentially of” two compositions, the overall method uses the “comprising” transitional language, which does not exclude other method steps, including administration of other compositions or compositions which do not affect the basic and novel characteristics of the two compositions. It is understood that “[t]he word ‘essentially’ [in ‘consisting essentially of’] opens the claims to the inclusion of ingredients which would not materially affect the basic and novel characteristics of appellant’s compositions as defined in the balance of the claim.” In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963) (emphasis in original).

Upon return of the application to the examiner, it is recommended that the examiner reconsider the relevance of the Veech disclosure at column 5, lines 39-61. Here, Veech describes administration of a composition of alpha-ketoglutarate and ammonium in addition to a metabolizable nitrogen containing compound.

Appellants ask the question in the Brief, at page 7, why one would employ a separate administration of a material such as ammonium which is known to cause metabolic acidosis when so demonstrated? The examiner should reconsider the claim interpretation and note that claim 1 does not appear to necessarily require administration of ammonium in a separate formulation. The appellants also ask, “if the presence of both α -KG and ammonium in the amino acid solution containing glutamate controls the redox state of the mitochondria, why would one be omitted?” Again it

does not appear from the claim interpretation that one of these compounds is required to be omitted, as it would appear that the compositions could be administered in the same formulation. Moreover, it does not appear that the claimed method excludes a step of administering other compounds such as glutamate, due to the claim language "comprising."

Finally, appellants argue in both the Brief and Reply Brief that the claims do not stand or fall together. Upon return of the application to the examiner, the examiner should either clearly establish on the record that appellants have not provided separate argument for individual claims or should address each individual claim separately, as appropriate. The examiner is also reminded that if appellants separately argue individual claims, the examiner must provide objective evidence that each of the claim limitations argued is known in the prior art. General statements such as "optimization of amounts or regimens... is within the skill of the artisan" (Answer, page 5) is not objective evidence. Patent examiners, in relying on what they assert to be general knowledge to negate patentability on the ground of obviousness, must articulate that knowledge and place it of record, since examiners must ascertain what would have been obvious to a person of ordinary skill in the art by finding relevant facts, assessing the significance of prior art, and making the ultimate determination of the obviousness issue. Failure to do so is not consistent with effective administrative procedure, examiners cannot rely on conclusory statements when dealing with particular combinations of prior art and specific claims, but must set forth the rationale on which

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they rely. See In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002). Thus, it is improper to rely on the “common knowledge and common sense” of a person of ordinary skill in art to find an invention obvious over a combination of prior art references, since the factual question of motivation to select and combine references is material to patentability, and cannot be resolved on subjective belief and unknown authority. In re Lee, 277 F.3d 1338, 1343-1344, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002).

CONCLUSION

The application is remanded to the examiner for interpretation of the claims and reconsideration each of the cited references in view of that claim interpretation. The examiner should consider all issues raised herein and take appropriate action. This remand to the examiner pursuant to 37 CFR § 41.50(a)(1) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)) is made for further consideration of a rejection. Accordingly, 37 CFR § 41.50(a)(2) applies if a supplemental examiner's answer is written in response to this remand by the Board.

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This application, by virtue of its “special” status, requires an immediate action.

Manual of Patent Examining Procedure (MPEP) § 708.01(d)(7th ed., July 1998).

REMANDED

Ellis

JOAN ELLIS
Administrative Patent Judge

Paul F. Schuman

TONI R. SCHEINER
Administrative Patent Judge

Demetrio J. Mills

DEMETRA J. MILLS
Administrative Patent Judge

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